General

Guideline Title

Treatment of miscellaneous idiopathic headache disorders (group 4 of the IHS classification) — report of an EFNS task force.

Bibliographic Source(s)

Evers S, Goadsby P, Jensen R, May A, Pascual J, Sixt G, EFNS task force. Treatment of miscellaneous idiopathic headache disorders (Group 4 of the IHS classification) -- report of an EFNS task force. Eur J Neurol. 2011 Jun;18(6):803-12. [150 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

The levels of evidence (class I-IV) supporting the recommendations and ratings of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

Pragmatic Recommendations for the Treatment of Headache Disorders Group 4 of the International Headache Society (IHS) Classification

Primary Stabbing Headache

- Indomethacin 25–50 mg twice a day (bid) (B)

- Choice: melatonin 3–12 mg in the evening or gabapentin 400 mg bid (C)

Primary Cough Headache

- Indomethacin 25–200 mg per day (B)
- Acetazolamide 125 mg three times a day (tid) (up to 200 tid) (B)
- Lumbar puncture with decrease in cerebrospinal fluid pressure (B)
- Methysergide 2 mg, naproxen 550 mg per day (C)

Primary Exertional Headache

- Avoidance of physical activity during heat or in high altitude
- Regular training and slow increase in activity in sports
- Normal body mass index
- Indomethacin 50–100 mg as short-term prophylaxis long-term prophylaxis (C)
    1. Choice: indomethacin 25–50 mg tid (B)
    2. Choice: propranolol 20–80 mg tid, flunarizine 10 mg per day (C)

Primary Headache Associated with Sexual Activity

- Avoidance of strong physical activity during sexual activity
- Indomethacin 50 to 75 mg as short-term prophylaxis (B)
- Propranolol (B)

Hypnic Headache

- Caffeine before sleeping (B)
    1. Choice: lithium 300–600 mg per day (B)
    2. Choice: indomethacin 100–150 mg per day, flunarizine 10 mg per day (C)

Primary Thunderclap Headache

- Acute phase: exclusion of subarachnoid haemorrhage and dissection by computed tomography (CT)/magnetic resonance imaging (MRI)/magnetic resonance angiography (MRA) scan, and lumbar puncture
- In the acute phase pain treatment with 500 mg paracetamol tid, metamizole 500 mg tid, or tramadol 200 mg tid (or similar opioid) after the acute phase in relapsing cases treatment with nimodipine 30–60 mg every 4 h over 14 days (C)

Hemicrania Continua

- Indomethacin 25 mg tid up to 200 mg per day (A)

New Daily-Persistent Headache

- Valproic acid 600–900 mg per day
- Amitriptyline up to 150 mg per day

Definitions:

Evidence Classification Scheme for a Therapeutic Intervention

Class I: An adequately powered prospective, randomized, controlled clinical trial with masked outcome assessment in a representative population or an adequately powered systematic review of prospective randomized controlled clinical trials with masked outcome assessment in representative populations. The following are required:

a. Randomization concealment
b. Primary outcome(s) is/are clearly defined
c. Exclusion/inclusion criteria are clearly defined
d. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched-group cohort study in a representative population with masked outcome assessment that meets a–e above or a randomized, controlled trial in a representative population that lacks one criteria a–e

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion

Rating of Recommendations for a Therapeutic Intervention

Level A (established as effective, ineffective, or harmful) requires at least one convincing class I study or at least two consistent, convincing class II studies.

Level B (probably effective, ineffective, or harmful) requires at least one convincing class II study or overwhelming class III evidence.

Level C (possibly effective, ineffective, or harmful) requires at least two convincing class III studies.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Headache disorders

Guideline Category

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurology

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To give recommendations for the treatment of headache disorders classified as the so-called group 4 headaches in the second edition of the International Classification of Headache Disorders (ICHD-II)
- To give drug and nondrug treatment recommendations for these headache disorders for both acute and prophylactic treatment

Target Population

Patients with headache disorders classified as the so-called group 4 headaches in the second edition of the International Classification of Headache Disorders (ICHD-II)

Interventions and Practices Considered

1. Drug treatment as appropriate
2. Lumbar puncture
3. Avoidance of physical activity during heat or at high altitudes
4. Regular training and slow increase in sports activities
5. Maintenance of normal body mass index
6. Avoidance of strong physical activity during sexual activity
7. Caffeine before sleeping
8. Computed tomography/magnetic resonance imaging/magnetic resonance angiography to rule out subarachnoid haemorrhage and dissection

Major Outcomes Considered

- Efficacy of treatments
- Degree of pain
- Incidence of headache
- Rate of remission
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search was performed using the reference databases MedLine, Science Citation Index, and the Cochrane Library; the key words used were 'headache' together with the respective description of the eight different headache types (last search in April 2010). All articles published in English, German, or French were considered when they described a controlled trial or a case report or series on the treatment of one of these headache disorders. In addition, a review book and the German treatment recommendations for these headache disorders were considered.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Classification Scheme for a Therapeutic Intervention

Class I: An adequately powered prospective, randomized, controlled clinical trial with masked outcome assessment in a representative population or an adequately powered systematic review of prospective randomized controlled clinical trials with masked outcome assessment in representative populations. The following are required:

a. Randomization concealment
b. Primary outcome(s) is/are clearly defined
c. Exclusion/inclusion criteria are clearly defined
d. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched-group cohort study in a representative population with masked outcome assessment that meets a–e above or a randomized, controlled trial in a representative population that lacks one criteria a–e

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The first draft of the manuscript was written by the chairman of the task force. All other members of the task force read the first draft and discussed changes by email. A second draft was then written by the chairman, which was again discussed by email. All recommendations had to be agreed to by all members of the task force unanimously. The background of the research strategy and of reaching consensus and the definitions of the recommendation levels used in this study have been described in the "Description of Methods Used to Collect/Select the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields.

The recommendations are based on the scientific evidence from clinical trials, from case reports, and on the expert consensus by the respective task force of the European Federation of Neurological Societies (EFNS).

Rating Scheme for the Strength of the Recommendations

Rating of Recommendations for a Therapeutic Intervention

Level A (established as effective, ineffective, or harmful) requires at least one convincing class I study or at least two consistent, convincing class II studies.

Level B (probably effective, ineffective, or harmful) requires at least one convincing class II study or overwhelming class III evidence.

Level C (possibly effective, ineffective, or harmful) requires at least two convincing class III studies.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The guidelines were validated according to the European Federation of Neurological Societies (EFNS) criteria (see the "Availability of Companion Documents" field).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

The treatment recommendations presented in this article are not based on controlled trials but most often based on case reports or series and on expert consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment of miscellaneous idiopathic headache disorders (the so-called group 4 headaches in the second edition of the International Classification of Headache Disorders [ICHD-II])

Potential Harms

- In some patients taking indomethacin, agents to protect the stomach are required such as antacid drugs, histamine-2 (H_2) antagonists, or proton pump inhibitor.
- Controls of the thyroid and renal functions are necessary in patients taking lithium.

Qualifying Statements

Qualifying Statements

This guideline provides the view of an expert task force appointed by the Scientific Committee of the European Federation of Neurological Societies (EFNS). It represents a peer-reviewed statement of minimum desirable standards for the guidance of practice based on the best available evidence. It is not intended to have legally binding implications in individual cases.

Implementation of the Guideline

Description of Implementation Strategy

The European Federation of Neurological Societies (EFNS) has a mailing list and all guideline papers go to national societies, national ministries of health, World Health Organisation, European Union, and a number of other destinations. Corporate support is recruited to buy large numbers of reprints of the guideline papers and permission is given to sponsoring companies to distribute the guideline papers from their commercial channels, provided there is no advertising attached.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Jun

Guideline Developer(s)

European Academy of Neurology - Medical Specialty Society

Source(s) of Funding

The present guidelines were developed without external financial support.

Guideline Committee

European Federation of Neurological Societies Task Force on Treatment of Miscellaneous Idiopathic Headache Disorders

Composition of Group That Authored the Guideline

Task Force Members: S. Evers, Department of Neurology, University of Münster, Münster, Germany; P. Goadsby, Headache Group, Department of Neurology, University of California, San Francisco CA, USA and UCL, Institute of Neurology, Queen Square, London, UK; R. Jensen, Danish Headache Center, Department of Neurology, Glostrup Hospital, University of Copenhagen, Copenhagen, Denmark; A. May, Department of Systems Neuroscience, University of Hamburg, Hamburg, Germany; J. Pascual, Area of Clinical Neuroscience, Service of Neurology, University Hospital "Central de Asturias", Oviedo, Spain; and G. Sixt, Department of Neurology, Regional Hospital, Bolzano, Italy

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Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available to registered users from the European Federation of Neurological Societies Web site .

Availability of Companion Documents

The following are available:

- Brainin M, Barnes M, Baron JC, Gilhus NE, Hughes R, Selmaj K, Waldemar G; Guideline Standards Subcommittee of the EFNS Scientific Committee. Guidance for the preparation of neurological management guidelines by EFNS scientific task forces – revised recommendations 2004. Eur J Neurol. 2004 Sep;11(9):577-81. Electronic copies: Available in Portable Document Format (PDF) from the European Federation of Neurological Societies (EFNS) Web site .

- Continuing Medical Education questions are available to registered users from the EFNS Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 20, 2012. The information was verified by the guideline developer on January 30, 2013. This summary was updated by ECRI Institute on July 10, 2013 following the U.S. Food and Drug Administration advisory on Valproate. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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